



FASULO BRAVERMAN & DI MAGGIO, LLP
ATTORNEYS AT LAW

Louis V. Fasulo, Esq. – NY & NJ
Samuel M. Braverman, Esq. – NY & NJ
Charles Di Maggio, Esq. – NY & CO

www.FBDMLaw.com
SBraverman@fbdmLaw.com
LFasulo@fbdmLaw.com

October 4, 2019

via electric filing

Hon. Judge Kimba M. Wood
United States District Judge
Southern District of New York
500 Pearl Street, Courtroom 26A
New York, New York 10007

Re: *United States v. Gordon Freedman, 18 CR 227 (KMW)*

Dear Judge Wood:

This letter is submitted on behalf of Defendant Gordon Freedman in support of a motion to: (1) preclude evidence, testimony and argument referring to Insys' guilty plea, Deferred Prosecution Agreement or civil settlement; (2) preclude evidence, testimony or argument comparing FDA-approved Subsys to heroin or "street drugs," and comparing Dr. Freedman or Insys personnel to "street-level" or any other kind of drug dealers; (3) preclude the Government from alleging or suggesting that Dr. Freedman, or any other physician mentioned at trial, was required to advise patients for whom they are prescribing Subsys that they are receiving or have received payments from Insys to present "Speaker Programs" regarding Subsys; (4) alleging Insys Reimbursement Center ("IRC") employees lied to insurance companies about patient diagnoses and medication histories in an effort to obtain insurance coverage for Subsys; (5) the Court order that the Government amend the Indictment at paragraphs fifty-one through fifty-two to include the full email exchange between the parties thereto; and permission to amend or supplement this submission or bring additional motions as necessary.

Background

Dr. Freedman stands charged by Indictment with violating and conspiring to violate the anti-kickback statute, and conspiring to commit honest services wire fraud. Dr. Freedman entered a plea of not guilty on March 16, 2018 and was released on a \$200,000 personal recognizance bond. Dr. Freeman's trial is scheduled to begin on November 4, 2019.

Discussion

I. The Court should preclude evidence, testimony and argument referring to Insys' guilty plea, Deferred Prosecution Agreement or civil settlement.

On June 7, 2019, Insys Pharma, Inc., a wholly-owned subsidiary of Insys Therapeutics, Inc. (the manufacturer of Subsys), pled guilty in the District of Massachusetts to five counts of mail fraud, admitting that it paid bribes to *certain* practitioners in order to induce them to write Subsys prescriptions. *United States v. Insys Therapeutics, Inc. and Insys Pharma, Inc.*, Case No. 1:19-cr-10191-RWZ, Dkt. Nos. 1 (Information, ¶ 11); Dkt. No. 17. On June 5, 2019, Insys Therapeutics, Inc. entered into a Deferred Prosecution Agreement ("DPA") based on an admitted Statement of Facts as well as a Corporate Integrity Agreement and a civil Settlement Agreement.¹ *Id.*, Dkt. No. 4; *see* Press Release dated June 5, 2019 issued by United States Attorney's Office, District of Massachusetts.

The five mail fraud counts to which Insys Pharma, Inc. admitted guilt were based on Insys' payments of bribes to a New Hampshire physician's assistant to conduct speaker programs when he did not make a presentation about the drug. *United States v. Insys Therapeutics, Inc.*, *supra*, Dkt. No. 1 (Information), ¶¶ 14, 18, 20, 22, 24, 26. The Information to which Insys Pharma, Inc. pled guilty stated that Insys Pharma and Insys Therapeutics used their

¹ In connection with the criminal proceeding, Insys Pharma, Inc. agreed to pay a fine of \$2 million and forfeiture of \$28 million. *United States v. Insys Therapeutics, Inc. and Insys Pharma, Inc.*, Case No. 1:19-cr-10191-RWZ, Dkt. No. 3, pp. 3-4. With respect to the civil settlement, Insys Therapeutics, Inc. agreed to pay \$195 million.

Speaker Program “to induce *certain* practitioners to write more prescriptions” in exchange for speaker fees (*Id.*, Dkt. No. 1 [Information, ¶ 11] [emphasis supplied]) – without specifying any particular practitioner aside from the New Hampshire physician’s assistant whose conduct formed the basis for the mail fraud counts. *Id.*, Dkt. No. 1 (Information), ¶¶ 32-33. The Statement of Facts upon which the Insys Pharma, Inc. Plea Agreement and the Insys Therapeutics, Inc. DPA were based states that “Insys paid bribes to *certain* practitioners . . . in order to induce *certain* practitioners to write unnecessary Subsys prescriptions.” *Id.*, Dkt. No. 3 (Statement of Facts), p. 2, ¶ 8 (emphases supplied). The Statement of Facts specifically cites to “*certain* practitioners in New Hampshire and Illinois” as conducting Speaker Programs which were solely a mechanism to pay bribes to these practitioners for prescribing Subsys. *Id.*, Dkt. No. 3 (Statement of Facts), p. 4, ¶ 14 (emphasis supplied).

Notably, neither the five mail fraud counts to which Insys Pharma pled guilty, nor the Statement of Facts upon which Insys Pharma’s Plea Agreement and Insys Therapeutics’ DPA were based, referenced any conduct by Dr. Freedman. Because Insys’ guilty plea and DPA were not based specifically on conduct relating to Dr. Freedman, evidence and argument relating to the foregoing should be precluded at Dr. Freedman’s trial, for several reasons. First, it would be inadmissible under *Crawford v. Washington*, 541 U.S. 36 (2004), violating the Confrontation Clause of the Sixth Amendment. Second, such evidence would be irrelevant to and therefore inadmissible against Dr. Freedman. Third, even if somehow relevant, the probative value of any such evidence would be substantially outweighed by unfair prejudice to Dr. Freedman.

The Sixth Amendment’s Confrontation Clause bars testimonial evidence where the witness is unavailable and the defendant did not have a prior opportunity to cross-examine the witness. *Crawford*, 541 U.S. at 68. *See also, United States v. Riggi*, 541 F.3d 94, 102 (2d Cir.

2008) (“*Crawford* holds that the Confrontation Clause bars ‘admission of testimonial statements of a witness who did not appear at trial unless he was unavailable to testify, and the defendant had had a prior opportunity for cross-examination’”) (quoting *Crawford*, 541 U.S. at 53-54). In *Riggs*, the admission of plea allocutions from eight non-testifying alleged co-conspirators was plain error under the circumstances, requiring vacatur of convictions. In this case, evidence relating to Insys Pharma, Inc.’s plea would be inadmissible under *Crawford*, and should be precluded. Further, the evidence should be precluded as irrelevant under Fed. R. Evid. 401 and 402. As stated, the charges to which Insys Pharma pled guilty and the admitted Statement of Facts of Insys Pharma and Insys Therapeutics are not based on conduct specifically relating to Dr. Freedman.

In addition, what Insys Therapeutics and Insys Pharma agreed *they* had done in connection with resolving the criminal and civil proceedings against them is unfairly prejudicial to Dr. Freedman suggesting Insys’ knowledge and intent should be imputed to Dr. Freedman without foundation. *See Kaplan*, 490 F.3d at 122 (District Court erroneously admitted witness’s testimony about his own and others’ knowledge of the fraud as circumstantial evidence that defendant knew about the fraud); *United States v. Garcia*, 291 F.3d 127 (2d Cir. 2002) (court abused its discretion in permitting witness to testify, without proper foundation, regarding what defendant allegedly meant in a conversation that purportedly contained coded references to drugs but which otherwise had a logical, coherent meaning). Such evidence would improperly lead the jury to conclude that Dr. Freedman shared the same knowledge and intent that Insys had, with no proper basis for such a conclusion.

Thus, even if somehow relevant, evidence and argument relating to the Insys plea, DPA and settlements should be precluded as unfairly prejudicial. The likelihood that jurors would

give such evidence undue weight or improperly hold Dr. Freedman liable because they believe that he should have known of Insys' conduct is substantial. As the Supreme Court has stated, “‘unfair prejudice’ [under Rule 403] . . . speaks to the capacity of some concededly relevant evidence to lure the factfinder into declaring guilt on a ground different from proof specific to the offense charged.” *Old Chief*, 519 U.S. at 180 (citation omitted). While we do not concede such evidence would be relevant, such evidence improperly would lure the jury into making determinations of guilt on grounds separate from proper evidence specific to the offenses charged. Thus, the danger of unfair prejudice would substantially outweigh any probative value. Accordingly, evidence and argument relating to Insys' guilty plea, DPA and civil settlement should be precluded.

II. The Court should preclude evidence, testimony and argument comparing FDA-approved Subsys to heroin or “street drugs,” and comparing Dr. Freedman or Insys personnel to “street-level” or any other kind of drug dealers.

The Indictment describes fentanyl as “a synthetic opioid that is classified as a Schedule II controlled substance under the Controlled Substances Act, meaning that it has a high potential for abuse. Fentanyl is approximately 50 to 100 times more potent than morphine.” Ind. ¶ 15. The Press Release issued by the United States Attorney for the Southern District of New York with respect to the Indictment states that the Defendant physicians “engaged in a malignant scheme to prescribe Fentanyl, a dangerous and potentially fatal narcotic 50 to 100 times more potent than morphine, in exchange for bribes in the form of speaker fees.” *See* Press Release dated March 16, 2018 issued by United States Attorney's Office, Southern District of New York.²

² DEPARTMENT OF JUSTICE, United States Attorney's Office, Southern District of New York, Five Manhattan Doctors Indicted For Accepting Bribes And Kickbacks From A Pharmaceutical Company In Exchange for

While it is anticipated that some description of the properties of Subsys – including its benefits and risks – will be permitted at trial, the Court should exclude irrelevant, highly inflammatory and unfairly prejudicial references to an “opioid crisis” or “opioid epidemic,” comparisons of Subsys to heroin or street drugs, and references to the physician defendants and/or Insys personnel as drug dealers. As the Indictment provides, Subsys is a Fentanyl spray approved by the FDA for the management of breakthrough pain in cancer patients (Ind. ¶ 14) – not a street drug. Use of such inflammatory language in this prosecution for alleged conspiracy to violate the anti-kickback statute and to commit honest services wire fraud would be irrelevant³ (Fed. R. Evid. 401 and 402) and unfairly prejudicial (Fed. R. Evid. 403).

Recent press releases issued by the Department of Justice in a number of cases have poisoned the public view of cases involving Subsys, characterizing the prescription fentanyl-based medication falsely as a street drug, claiming Insys is responsible for an opioid crisis/epidemic and referring to Insys executives as drug traffickers.

On June 5, 2019, in connection with Insys’ agreement to enter into a global resolution of the Government’s criminal and civil investigations of Insys, the United States Attorney’s Office for the District of Massachusetts issued a press release making multiple references to the “opioid epidemic,” stating that Insys was “being held responsible for its role in fueling the opioid epidemic,” assuring “families and communities ravaged by this epidemic that the [DOJ] will

Prescribing Powerful Fentanyl Narcotic (Mar. 16, 2018), <https://www.justice.gov/usao-sdny/pr/five-manhattan-doctors-indicted-accepting-bribes-and-kickbacks-pharmaceutical-company>.

³ Also, it would be inaccurate to directly link any alleged opioid crisis or epidemic to prescription drugs. *See, The Truth about the US ‘Opioid Crisis’ – Prescriptions Aren’t the Problem*, The Guardian (U.S. Edition), (Nov. 7, 2017), <https://www.theguardian.com/commentisfree/2017/nov/07/truth-us-opioid-crisis-too-easy-blame-doctors-not-prescriptions>.

continue to act forcefully ...,” and stating that DOJ’s “goal is to bring about an end to the tragic epidemic of opioid addiction.”⁴

Similarly, on May 2, 2019, in connection with the convictions of the founder and former executives of Insys, *United States v. Babich, et al.*, Case No. 16-cr-10343 (ADB), the United States Attorney for the District of Massachusetts issued a press release stating: “Just as we would street-level drug dealers, we will hold pharmaceutical executives responsible for fueling the opioid epidemic . . . This is a landmark prosecution that vindicated the public’s interest in staunching the flow of opioids into our homes and streets.”⁵

Highly inflammatory references have also been made by the DOJ in recent press releases related to other fentanyl-based prescription medications and pharmaceutical company manufacturers and distributors.

Notably, on April 11, 2019, the United States Attorney’s Office for the Southern District of New York issued inflammatory statements in connection with a separate indictment filed against Dr. Gordon Freedman (19 Cr. 249 [AJN]) charging him with distributing a fentanyl-based TIRF product (as well as other controlled substances) to a particular patient, causing the patient to suffer a fatal overdose. The DOJ press release compared the prescription fentanyl to street drugs contributing to the opioid epidemic: “Everyone knows the inherent danger in buying and selling drugs on the street, but when doctors overprescribe legal substances in lethal quantities, they too contribute to the overall drug epidemic. These drugs pose a real threat to our

⁴ Department of Justice, United States Attorney’s Office, District of Massachusetts, Insys Therapeutics Agrees to Enter into \$225 Million Global Resolution of Criminal and Civil Investigations, (June 5, 2019), <https://www.justice.gov/usao-ma/pr/insys-therapeutics-agrees-enter-225-million-global-resolution-criminal-and-civil>.

⁵ On May 2, 2019, all defendants were found guilty on the sole charge of RICO conspiracy.

society. We hope to send the message today that there's no quick fix for doctors who hide behind their prescription pad—this is criminal activity, and it will be treated as such.”⁶

On March 12, 2019, in announcing the issuance of a complaint against individuals who allegedly sold fentanyl and carfentanil on the “dark web,” the United States Attorney for the Southern District of New York stated, “[f]entanyl is a chief culprit in the opioid crisis” (Press Release in *United States v. Richard Castro*, dated March 12, 2019). The press release also compared fentanyl to heroin, stating that “[f]entanyl is a synthetic opioid that is significantly stronger than heroin.” *Id.*

On April 23, 2019, in announcing charges brought against Rochester Drug Co-Operative, Inc., “one of the 10 largest pharmaceutical distributors in the United States,” and two of its former executives, for unlawfully distributing fentanyl and oxycodone, the United States Attorney for the Southern District of New York stated: “This prosecution is the first of its kind: executives of a pharmaceutical distributor and the distributor itself have been charged with drug trafficking, trafficking the same drugs that are fueling the opioid epidemic that is ravaging this country. Our Office will do everything in its power to combat this epidemic, from street-level dealers to the executives who illegally distribute drugs from their boardrooms.”

While the Indictment in this case does not specifically compare fentanyl-containing Subsys to heroin or to “street drugs,” or refer to an “opioid crisis” or “opioid epidemic” or refer to the physician defendants as drug dealers, given that the DOJ and the U.S. Attorney’s Office for the Southern District of New York have publicly highlighted such comparisons and references, in the exercise of caution, Dr. Freedman seeks to preclude the Government at trial in our case from: comparing Subsys to heroin or street drugs, and comparing the physician

⁶ Department of Justice, United States Attorney’s Office, Southern District of New York, Manhattan Doctor Indicted For Diverting Drugs And Causing Patient’s Overdose Death, (April 11, 2019), <https://www.justice.gov/usao-sdny/pr/manhattan-doctor-indicted-diverting-drugs-and-causing-patient-s-overdose-death>.

Defendants or Insys personnel to drug dealers. Use of such inflammatory language in evidence or argument in Dr. Freedman's case would be irrelevant and unfairly prejudicial.

In sum, the risk is substantial that a jury would be influenced improperly by the inflammatory nature of the aforementioned references. The Advisory Committee's Notes to Rule 403 state, in part, that " 'Unfair prejudice' within its context means an undue tendency to suggest decision on an improper basis, commonly, though not necessarily, an emotional one." Clearly, such inflammatory references would risk improper appeal to jurors' emotions, creating a risk that the jury would be influenced to make a decision based on something other than a proper factual basis. Accordingly, any such references, evidence or argument should be precluded at trial.

III. The Court should preclude the Government from alleging or suggesting that Dr. Freedman, or any other physician mentioned at trial, was required to advise patients for whom they are prescribing Subsys that they are receiving or have received payments from Insys to present "Speaker Programs" regarding Subsys.

As an initial matter, pharmaceutical companies regularly contract with physicians to present programs and speak with health care providers in order to educate them about particular drugs. "Speaker programs enlist physicians, for pay, to speak to other physicians about FDA-approved drug use." *United States v. Caronia*, 703 F.3d 149, 156 (2d Cir. 2012). Speaker Programs are permissible; they are not per se illegal. *See* 42 C.F.R. § 1001.952(d) (defining "personal services" contracts as a permissible, non-criminal "payment practice").⁷

⁷ In *United States v. Babich*, the Court gave the following preliminary charge to the jury (Tr., Jan 28, 2019, p. 31):

During the trial you may hear evidence that Insys paid health care practitioners and recorded that those payments were for health care practitioners to speak to other health care professionals about their experience with Subsys. Paying a health care practitioner to speak to other health care professionals about their experience with Subsys is not in and of itself illegal. Such speaker programs properly done are a way for pharmaceutical companies to help educate and inform health care professionals about the benefits, risks and appropriate uses of medications.

The Indictment in this case does not allege that the physician Defendants had an affirmative duty to tell patients for whom they prescribed Subsys that the physician was a paid speaker for the manufacturer, Insys – for good reason, because there is no such duty. Therefore, the Government should be precluded from arguing or suggesting that there is such a duty.

Notably, such payments are publicly disclosed. The Physician Payments Sunshine Act, 42 U.S.C. § 1320a-7h (the “Sunshine Act”), requires public reporting by pharmaceutical companies of “a payment or other transfer of value” to physicians, including payments for services (such as speaker programs) and the value of items provided to physicians (such as meals). The information is publicly available on the Centers for Medicare and Medicaid Services (“CMS”) website at <https://openpaymentsdata.cms.gov/> and on the propublica.org website. Thus, the amounts paid to physicians by Insys were not hidden or concealed, and there is no claim in the Indictment that Insys falsely reported payments to the physicians in our case.

Moreover, the American Medical Association (“AMA”) recognizes the potential scientific benefits of financial interactions between physicians and drug manufacturers and the benefits of transparent reports of such financial interests, stating:

There are many interactions between physicians and manufacturers of drugs, medical devices, and medical supplies that benefit patients and advance the art and science of medicine. The Sunshine Act transparency reports provide patients and the public with information on the financial interactions of physicians and industry. These interactions often drive innovation, discovery and changes in medical practice that promote better patient outcomes. The congressional sponsors of the Affordable Care Act (ACA) reporting provisions have stated that this process is not designed to stop, chill, or call into question beneficial interactions between physicians and industry, but to ensure that they are transparent.⁸

⁸ *Sunshine Act: Physician financial transparency reports*, American Medical Association, available at <https://www.ama-assn.org/practice-management/medicare/physician-financial-transparency-reports-sunshine-act>.

Critically, the AMA does not advise that a physician must affirmatively tell a patient that he or she is a paid speaker for a pharmaceutical program or product. Rather, the AMA only advises only that “When a patient asks about this topic,” the physician should be candid, being careful to “enhance the patient’s understanding without compromising trust or the physician-patient relationship.” *Id.*, p. 3.

In sum, to suggest or claim that a physician is required affirmatively to advise a patient that he receives or has received payments from a pharmaceutical company for speaker programs is incorrect, misleading and unfairly prejudicial. Accordingly, any such proposed evidence, suggestion or argument should be precluded at trial.

IV. The Court should preclude the Government from alleging that Insys Reimbursement Center (“IRC”) employees lied to insurance companies about patient diagnoses and medication histories in a effort to obtain insurance coverage for Subsys.

In the *Babich* case against Insys executives, the RICO conspiracy charge included allegations that Insys’ IRC personnel, among other things, presented false diagnoses to insurance companies, pretended they were calling from physicians’ offices, and spoke with insurance companies in a calculatedly misleading manner.

While relevant to the charge against the Insys executives, any such evidence about what IRC employees allegedly did is irrelevant to the charges against Dr. Freedman. Notably, Dr. Freedman is not charged with insurance fraud nor is it alleged that that he aided the IRC in improperly or misleadingly seeking insurance coverage for prescriptions. Without any claim that Dr. Freedman aided or even had knowledge of the alleged actions by IRC employees to improperly obtain insurance coverage for Subsys prescriptions, evidence of the IRC’s alleged fraudulent behavior should be precluded in our case as irrelevant. Fed.R.Evid. 402. *See Kaplan,*

490 F.3d at 120 (“evidence regarding the knowledge of individuals other than the defendant should be admitted only if there is some other evidence in the record – concerning, for example, the nature of the fraud or the relationship of the parties – from which to conclude that the defendant would have the same knowledge”). The Government does not claim that Dr. Freedman knew what Insys IRC employees told insurance companies about his patients in order to obtain coverage for Subsys prescriptions, much less that he aided in the making of any misstatements.

Moreover, even if there were some relevance concerning the evidence of the IRC’s alleged fraudulent behavior, it would be far outweighed by the risk of unfair prejudice to Dr. Freedman, warranting preclusion. Fed. R. Evid. 403. In *Kaplan*, where a witness testified about others’ knowledge of a fraudulent business but there was a lack of evidence connecting the third parties’ knowledge of the fraudulent scheme to the defendant, the Second Circuit found the evidence had minimal relevance at best, but even if sufficiently relevant, the probative value of the evidence was substantially outweighed by the risk of unfair prejudice and should not have been admitted. “[T]he likelihood that jurors would render a decision on an improper basis by giving this testimony undue weight or improperly holding [the defendant] liable because they believed he should have known of the fraud – was great.” *Kaplan*, 490 F.3d at 122. Accordingly, evidence and argument relating to IRC employees’ alleged fraud to obtain insurance coverage for patients’ Subsys prescriptions should be precluded.

V. The Court should order that the Government amend the Indictment at paragraphs fifty-one through fifty-two to include the full email exchange between the parties thereto.

The factual allegation section of Count One of the indictment contains a reference to an email exchange between Dr. Freeman and RSM-2 (Regional Sales Manager 2) on or about

March 29, 2013. (Ind. ¶¶ 51-52). The Indictment alleges that RSM-2 emailed Dr. Freedman to inform that Dr. Freeman had been allocated additional speaker programs because Insys wanted Subsyst prescriptions to increase in the second quarter of 2013. *Id.* The Indictment alleges that Dr. Freeman responded “Got it.” Upon information and belief, the Government will use the email from RSM-2 and Dr. Freeman’s response as proof of knowledge and agreement of the conspiracy.

The Indictment intentionally omits highly relevant portions of the email from RSM-2, as well as Dr. Freedman’s response that, in its absence, completely change the context of the exchange. The full exchange is annexed hereto at Exhibit A. A review of the full exchange makes clear that, even viewing the evidence in the light most favorable to the Government, RSM-2’s email and crux of Mr. Freedman’s response was to confirm the dates of the speaker engagements, and not that Dr. Freedman was agreeing to violate anti-kickback laws.

This Court should order the Government to amend the Indictment provided to the jury at trial to include the full context of these emails. Omitting the full context of the email exchange was a strategic decision by the Government at the charging phase, but when presented to the jury out of context it serves only to improperly inflame the jury and impermissibly shift the burden to Dr. Freeman to disprove the Government’s theory or provide an alternate theory as to why this email is not evidence of criminality.

Conclusion

For the reasons stated herein, this Court should grant the aforementioned relief sought.

Dated: October 4, 2019
New York, New York

Respectfully Submitted,

Attorneys for Defendant Dr. Freedman
FASULO, BRAVERMAN & Di MAGGIO, LLP
225 Broadway, Suite 715
New York, NY 10007
(212) 566-6213

By: /s/ Samuel Braverman
Samuel M. Braverman, Esq.

TO: Clerk of the Court (via electronic filing)
United States District Court
Southern District of New York
500 Pearl Street
New York, New York 10007

United States Attorney's Office (via electronic filing)
Southern District of New York
1 Saint Andrew's Plaza
New York, New York 10007